



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MUHAMMAD CHISHTI et al.

Application No.: 10/718,779

Filed: November 20, 2003

For: COMPUTER AUTOMATED
DEVELOPMENT OF AN
ORTHODONTIC TREATMENT
PLAN AND APPLIANCE

Customer No.: 46718

Confirmation No. 1523

Examiner: Wilson, John

Technology Center/Art Unit: 3732

DECLARATION UNDER 37 C.F.R § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I am a licensed orthodontist and have maintained an active clinical practice in the field of orthodontics since 1999. I have been employed by Align since 1998 and currently I hold the position of Senior Director of Clinical Affairs at Align Technology, Inc. ("Align"), the assignee of record for U.S. Patent Application No. 10/718,779.

2. The information below is based upon both my direct knowledge of the Invisalign® product, marketing, sales and the orthodontic market as well as information provided to me by persons at Align. The following facts are within my personal knowledge except as those that have been stated on information and belief and as to those I am informed and believe that they are true. If called as a witness I could, and would, testify competently to the foregoing in a court of law.

3. I received a Bachelor of Science Degree from Stanford University in 1992, a Doctor of Dental Surgery from University of California, Los Angeles in 1996, and a Specialty Certificate in Orthodontics and Masters Degree in Oral Biology from University of California, San Francisco in 1999.

4. Essentially, all of Align's business is focused on its Invisalign® aligners. Invisalign® aligners is a series of typically three or more aligners designed to move teeth incrementally from one position to the next position. Through these incremental movements, teeth are repositioned from an initial position to a final position prescribed by an orthodontist or dentist.

5. Align's Invisalign® product has been very successful in the orthodontic market. Traditionally, patients had to wear braces for comprehensive orthodontic treatment. A number of patients, particularly adults, avoided orthodontic treatment because of aesthetic concerns associated with fixed orthodontic braces. Additionally, traditional orthodontic treatment was often painful as well as inconvenient (restrictions to diet and certain sports activities, plus the occasional emergency visit to fix a broken wire or loose band/bracket. Brushing and flossing of teeth was also more difficult. As a result, there was a need in the market for a more aesthetic orthodontic appliance that required little to no adjustment and made eating, brushing and flossing easier. Orthodontists were looking for an appliance that could reduce their chair time with patients (and hence increase their practice capacity and productivity), draw more new patients into the practice, reduce the pain and inconveniences associated with fixed orthodontic treatment, and better promote the health of the teeth and gums during treatment through ease of brushing and flossing. Align's Invisalign® system meets each of these needs; as a result, it has found considerable success in the market.

6. This commercial success is directly related to the features that are described in Align's U.S. Patent Application no. 10/718,779 and the corresponding pending claims, as well as in other pending applications and issued patents owned by Align.

7. Since the introduction of Align's Invisalign® system, it has created a revenue stream of about \$400,000 for 1999, \$6.7M for 2000, \$44.8M for 2001, \$69.7M for 2002, \$122.7M for 2003, \$172.8M for 2004, and \$207.1M for 2005. The revenue has increased dramatically over the relevant years. True and correct copy of Align documentation regarding Align's revenue is attached hereto as Exhibit A.

8. Additionally, the number of new patients using Align's product has increased dramatically since the introduction of the product. True and correct copy of Align documentation regarding the number of new patient start figures is attached hereto as Exhibit B.

9. Along with the dramatic increase in revenue and number of new patients, the cumulative number of individual aligners shipped by Align has increased dramatically from 1999 to 2005. True and correct copy of Align documentation regarding Align's cumulative number of individual aligners shipped is attached hereto as Exhibit C.

10. Additionally, the number of doctors starting cases using Align's product has increased from 2003 to 2005. True and correct copy of Align documentation regarding the number of doctors starting cases is attached hereto as Exhibit D.

11. The steady increase of the number of doctors trained in the Invisalign system from 2002 to 2005 also shows the success of Align's Invisalign® since its introduction. The number includes doctors who did not previously perform orthodontic treatments before being trained in the Invisalign® system. True and correct copy of Align documentation regarding the number of doctors trained is attached hereto as Exhibit E.

12. Align's Invisalign® system has also received a number of awards: "2002 Medical Design Excellence Award," presented by Canon Communications LLC; "2003 Phoenix Emerging Growth Company Award" at the 10th annual "Phoenix: The Medical Device and Diagnostic Conference for CEO's"; and "2004 Medical Devices Technology Leadership of the Year Award" from Frost & Sullivan. True and correct copies of some documentation regarding these awards are attached hereto as Exhibits F–H.

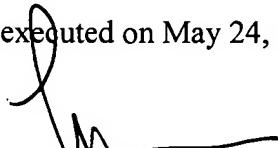
13. The success of Align's Invisalign® system is also reflected in praises and acceptance by professionals and academia. For example, in a textbook titled "Orthodontics and Dentofacial Orthopedics" the Invisalign® system is featured over eight pages as a new technology in a chapter discussing "Invisible Retainers and Aligners." True and correct copy is attached as Exhibit I.

14. Moreover, I believe the success of the Invisalign System has been primarily due to the innovative product and method of manufacture as covered by Align's U.S.

Patent Application no. 10/718,779 and other pending applications and issued patents of Align and not primarily due to expenditure of advertising. As shown in the attached Exhibit J, the average advertising expense as a percentage of total revenue for the past four complete fiscal years from 2002-2005 has been less than 5.5%.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that this Declaration was executed on May 24, 2006.

Date: 5-24-2006

By: 

Eric Kuo

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